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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/508,892	03/17/00	HUATAN H	PC9455A

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EXAMINER	
LEVY, N	
ART UNIT	**PAPER NUMBER**
1616	9

DATE MAILED: 08/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/508892	HAYAN
Examiner	**Group Art Unit**
NOLAN	1616

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3/17/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1 – 24 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 – 24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been ☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Receipt is acknowledged of IDS, Priority Papers, and Amendment, each of 3/17/00.

There is no Abstract.\

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 18, 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Low" is indefinite absent quantification. Claim 1 is ambiguous; are there more than bulking agent required, or not. "Adapted" is ambiguous as to how adapted in terms of the meets and bounds of the intended claim limitations "suitable" is indefinite, likewise (claim 12). Claim 12 is ambiguous and indefinite--no sterilization is required, if so, is or radiation the only mode?

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is insufficient guidance for one in the art to know when this implant is needed as opposed to any other treatment modality.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-5, 8, 10, 12, 14-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu et al EPO 537998.

Any desired solid shaped implant (p. 5, lines 50-rod shaped; P. 3, lines 14-6, 29, 30) with antioxidants, lubricants and fillers--the instant bulking agent (p. 5, line 17) with calcium stearate, similar to magnesium stearate (line 19) at 0.1-10%, with drug at .1 to 60% (line 19-27) and polymer at up to 98%; thus the instant drug with polymers as tableting excipient is over 99%. The drugs include the instant avermectinis/milhemyanis as preferred (p. 7, bottom). Although not specified, nothing precludes tableting aids or sterilizing--the compositions are suitable for sterilizing, absent any showing by applicant these are not so, pressure molding in fact is shown p. 5, lines 37-48; also the rod form shown is seen as adapted for use as desired, including implantation into cattle ears, although not so expressed.

Claims 1-3, 8, 10-16, 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Senbo-5567429.

Tableting excipients and bulking agents--starch, polyvinyl pyrrolidone, BHT, BHA, (col. 3, lines 36-44) sugars (line 61), is prepared with 0.001 to 95% drug-parasiticidal (col. 3, lines 8, 9), in the form of a rod Example 4). Tablet forms are also shown (example 3). The forms are adapted and suitable for implantation and irradiation, and of a size for subcutaneous implantation. Future intended use is not given patentable weight.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shih et al EPO 473223 in view of Hsu, Roorda 5543156 and Senbo.

Shih provides implants of the instant rods of parasiticidal form to animals, sheep, cattle, that need it (p. 5, lines 50-line 54, p. 6) of up to 100% drug (lines 6, 6, p. 7) excipients include bulking agents, at 0.01-20% (line 55, p. 7), BHT (top, p. 8). Mg stearate, lactose, glycolate, PVP, and sterilization is not disclosed. This office takes notice that these excipients are standard in the art, as is sterilization of implantables, and would be within the purview of one of ordinary skill in the art to practice as optimization parameters.

Roorda, for examples utilizes equivalently Ca or Mg stearate (col. 5, top) as polymer (PVP-Col. 4, line 1) excipient in implantable devices, rods (col. 9, lines 5-8) lactose is also used (Fig. 9) parasiticides, biocides, and sterilization agents are present (col. 6, lines 3, 4). Hsu, above teach the similar avermectin use for animal parasite control, while Senbo is cited to show excipient inclusion in tableting and pelleting.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize insecticidal protection of animals in need thereof to use Shih and Hsu implants, modified as desired to optimize production, safety to host by sterilization as is known in the implantation arts to do, and use of particular excipients for stability and degradation as shown by Senbo and Roorda.

The primary reference discloses the essence of the instant invention as claimed, but does not specify each and every element of the instantly claimed methods and compositions. However, the secondary reference directed at the same method and compositions to solve the same problem of the primary reference do provide these additional elements.

There is no distinguishing disclosure of the instant composition as providing any unusual and/or unexpected results obtained since the prior art is well aware of the use of implants for active agents or combinations thereof for controlled release formulations.

The selection of the instant non-critical control ingredients and concentrations are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the

concentration each ingredient to optimize the effect desired and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday to Friday from 7 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy:mv

August 14, 2001

NEIL S. LEVY
PRIMARY EXAMINER